UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

)
AMGEN INC.,)
Plaintiff,)) Civil Action No.: 05-12237 WGY
v.)
)
F. HOFFMANN-LAROCHE)
LTD., a Swiss Company, ROCHE)
DIAGNOSTICS GmbH, a German)
Company and HOFFMANN LAROCHE)
INC., a New Jersey Corporation,)
Defendants.)))

AMGEN'S BENCH MEMORANDUM CONCERNING THE APPROPRIATE JURY INSTRUCTION ON INFRINGEMENT AND "ADDITIONAL ELEMENTS

Amgen Inc. respectfully requests that the Court adopt Amgen's proposed jury instruction XIII.A.2 "Infringement of '868 Claims 1-2, '698 Claims 6-9, and '349 Claim 7" This memorandum explains how additional elements in the accused product or process that are not recited in the claims should be treated for purposes of determining infringement.

As the Federal Circuit explained in A.B. Dick Co. v. Burroughs Corp.,²

It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.

The infringement inquiry requires the court to determine if each claim limitation is present in the

¹ Attached as Exhibit A is Amgen's amended proposed jury instruction XIII.A.2. "Proposed Instruction for Infringement of '868 Claims 1-2, '698 Claims 6-9, and '349 Claim 7."

² 713 F.2d 700, 703 (Fed. Cir. 1983) (citation omitted).

accused product, not whether each feature or component of the accused product is present in the claim.³ The presence of additional elements in the accused product or process that are not recited in the claims does not negate infringement.⁴ The Federal Circuit has criticized noninfringement arguments that - like Roche's argument here - are based upon a feature of the accused product or process missing from the claims:

That view would stand the law of infringement on its head, and would fatally undermine the long-established legal principle that non-infringement is shown when an element or step in the claims is missing from the accused product or process, not vice versa.⁵

In SunTiger, Inc. v. Scientific Research Funding Group,⁶ the Federal Circuit reversed a grant of summary judgment of non-infringement in favor of the defendant in a case that is closely on point. The claims at issue were to optical lenses for sunglasses that screened out certain wavelengths of visible light. Defendants' accused lenses contained an additional element - a gray gradient surface coating that further reduced the amount of light passing through the accused lenses. Due to the addition of the gray gradient, only part of the lenses (the right bottom portion) met the recited properties of the claims.

The Federal Circuit held that the trial court erred in finding no infringement, explaining:

The district court's error lies in the fact that we have never required that a claim read on the entirety of an accused device in order to infringe. If a claim reads merely on a part of an accused device, that is enough for infringement. . . . Any

³ Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482-83 (Fed. Cir. 1984); see also Nazomi Communications, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1372 (Fed. Cir. 2005); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 121-22 ("While the specified elements following 'comprise' and 'comprising' are essential, additional elements may be added to the specified elements and still form a construct within the scope of the claim."), aff'd in relevant part, 314 F.3d 1313, 1351-52 (Fed. Cir. 2003).

⁴ Amstar, 730 F.2d at 1482 ("Modification by mere addition of elements of functions, whenever made, cannot negate infringement without disregard of the long-established, hornbook law ").

⁵ *Id.* at 1484.

⁶ 189 F.3d 1327, 1336-37 (Fed. Cir. 1999).

other reasoning would allow an infringer to avoid infringement merely by adding additional elements to an infringing device.

The rule that additional elements will not negate infringement applies unless the claim language explicitly excludes the presence of additional elements, or the inventor distinguished the claimed invention by reference to its exclusion of such structures.⁸ None of those exceptions apply to the asserted claims-in-suit.

The Federal Circuit's decision in Northern Telecom Ltd. v. Samsung Elecs. Co., is instructive. The claim at issue was directed to a process for etching aluminum and aluminum oxide on semiconductor devices using a chemical process called plasma etching. The trial court had construed the term "aluminum and aluminum oxide" to be limited to "pure aluminum and its native layer of aluminum oxide" and to exclude aluminum silicon alloys. 10 The defendant argued that it did not infringe because its process etched an aluminum silicon alloy. The trial court nevertheless granted summary judgment of infringement, and the Federal Circuit affirmed, because pure aluminum was present in the aluminum silicon alloy that was etched in the accused process. 11 The additional etching of the silicon and copper in the alloy was "simply an additional step or aspect of the accused process and thus did not prevent a finding of literal infringement."¹²

The Federal Circuit in Northern Telecom also rejected a non-infringement argument based on the fact that the accused etching process used both the claimed plasma etching as well

⁷ *SunTiger*, 189 F.3d at 1336.

⁸ See Crystal Semiconductor v. TriTech Microelectronics Intern., Inc., 246 F.3d 1336, 1348-51 (Fed. Cir. 2001).

⁹ 215 F.3d 1281 (Fed. Cir. 2000).

¹⁰ *Id.* at 1290.

¹¹ *Id.* at 1290, 1297.

¹² *Id.* at 1290.

as ion bombardment. 13 As the Federal Circuit explained,

[I]f a patent requires A, and the accused device or process uses A and B, infringement will be avoided only if the patent's definition of A excludes the possibility of B. Statements simply noting a distinction between A and B are thus unhelpful: what matters is not that the patent describes A and B as different, but whether, according to the patent, A and B must be mutually exclusive.¹⁴

Here, the patents do not exclude the presence of additional structure or steps. To the contrary, in the context of the term "human erythropoietin" in '422 claim 1, the Court previously ruled that the "specification does not define 'erythropoietin' by reference to the presence or absence of any attached molecules" and that "the specification expressly contemplates that additional molecules may be attached to 'human erythropoietin.'" With respect to the term "comprising the steps of" or "comprising the step of" in the process claims of '868 claims 1-2, '698 claims 6-9, and '349 claim 1, the Court construed the term "comprising" to mean "containing the named elements," rejecting Roche's request to construe the claims to mean that "any other additional step is outside the claim."

Accordingly, Amgen's proposed instructions with respect to infringement should be adopted because the instructions make clear that, by itself, the presence of additional elements or steps is not a basis for finding non-infringement.

While the existence of additional steps is not legally relevant to whether the limitations of the asserted process claims are literally satisfied, those additional steps may be relevant to whether the product of the claimed processes is materially changed prior to importation. The issue of "materially changed" and "trivial and non-essential component" is separately discussed

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¹³ *Id.* at 1296.

¹⁴ *Id.* at 1296-97 (citations omitted).

¹⁵ Amgen, Inc. v. F. Hoffman-LaRoche Ltd., 494 F. Supp. 2d 54, 63 (D. Mass. 2007).

¹⁶ *Id.* at 69.

in Amgen's concurrently filed Bench Memorandum Concerning the Appropriate Jury Instruction on 35 U.S.C. § 271(g).

Dated: October 9, 2007 AMGEN INC.,

By its attorneys,

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CERTIFICATE OF SERVICE

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/s/ Michael R. Gottfried

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